

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAKE CHARLES DIVISION**

RHONDA BREAUX,

CIVIL CASE No. 2:23-cv-01365

Plaintiff,

v.

JUDGE JAMES D. CAIN, JR.

NOVO NORDISK A/S, NOVO NORDISK
NORTH AMERICA OPERATIONS A/S,
NOVO NORDISK US HOLDINGS INC.,
NOVO NORDISK US COMMERCIAL
HOLDINGS INC., NOVO NORDISK INC.,
NOVO NORDISK RESEARCH CENTER
SEATTLE, INC., NOVO NORDISK
PHARMACEUTICAL INDUSTRIES LP,

MAGISTRATE JUDGE KATHLEEN KAY

Defendants.

**PLAINTIFF'S MEMORANDUM IN OPPOSITION TO THE NOVO NORDISK
DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT**

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INTRODUCTION

This Court should deny the Novo Nordisk Defendants' ("Novo Nordisk") motion to dismiss. Plaintiff has alleged that Novo Nordisk knew of the risk that Ozempic could cause gastroparesis (stomach paralysis) and yet opted not to warn that 1) Ozempic could cause gastroparesis, 2) patients may not know that they have gastroparesis, or 3) symptoms like vomiting and nausea may indicate that a patient has gastroparesis. As a result, Plaintiff's doctor did not know of the risk and prescribed Ozempic to Plaintiff, causing Plaintiff's gastroparesis and its sequelae, such as stomach pain, gastrointestinal burning, being hospitalized for stomach issues on several occasions including visits to the emergency room, and violent vomiting, requiring additional medications to alleviate her extreme and violent vomiting, and throwing up whole food hours or even days after eating.

Plaintiff has adequately pled both her failure-to-warn and express warranty claims under the Louisiana Products Liability Act ("LPLA"). Novo Nordisk argues that Plaintiff has not fully anticipated and adequately pled around its learned intermediary defense, but this defense requires Novo Nordisk to come forth with evidence—something it has not done and cannot do at this stage. The Fifth Circuit has held that a manufacturer can prevail on this defense only where the prescriber has unequivocally *testified* that a different warning would not have made a difference. *Stahl v. Novartis*, 283 F.3d 254, 267 (5th Cir. 2002). Thus, Novo Nordisk's argument is premature. In any event, as explained herein, Plaintiff has pled that the inadequate warning caused her doctor's prescription decision. Likewise, for the express warranty claim, Plaintiff has pled that Novo warranted that Ozempic was safe to use while downplaying and concealing the risk of a life-threatening condition (gastroparesis). This Court has found similar allegations sufficient in prior cases and should do so again here.

COMPLAINT ALLEGATIONS

Ozempic (semaglutide) is a glucagon-like peptide-1 receptor agonist (GLP-1RA). Novo Nordisk manufactures Ozempic to treat type 2 diabetes. Complaint ¶¶ 27-29. Plaintiff used Ozempic that had been prescribed by her physician for approximately two months before stopping use in or around October 2022. Complaint ¶¶ 10-11. As a result of using Ozempic, Plaintiff suffered from gastroparesis and its sequelae. Complaint ¶ 12. Gastroparesis (“paralyzed stomach”) is a condition in which the stomach muscles fail to move food into the digestive tract, leaving undigested food in the stomach. Complaint ¶¶ 6-7. Due to her gastroparesis, Plaintiff suffered from stomach pain, gastrointestinal burning, being hospitalized for stomach issues on several occasions including visits to the emergency room, and violent vomiting, requiring additional medications to alleviate her extreme and violent vomiting, and throwing up whole food hours or even days after eating. Complaint ¶ 13.

LEGAL STANDARD

A complaint must contain a “short and plain statement of the claim showing that the pleader is entitled to relief.” FRCP 8(a)(2). Plaintiff must state a plausible claim by alleging “factual content that allows the court to draw the reasonable inference that the defendant is liable.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Plaintiff need not make “detailed factual allegations,” *Bell Atl. v. Twombly*, 550 U.S. 544, 555 (2007), and the Court must “draw all reasonable inferences in favor of the plaintiff.” *Frye v. Anadarko*, 953 F.3d 285, 290-91 (5th Cir. 2019). Rule 8 “simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence” to support liability. *Twombly*, 550 U.S. at 556.

ARGUMENT

I. The Complaint is not a shotgun pleading.

The Complaint bears no resemblance to a shotgun pleading where defendants must “fish a

gold coin from a bucket of mud.” *Lawson v. Lifepoint*, 2017 WL 4365814, at *4 (W.D. La. Sept. 29, 2017). “Whatever validity that concept has in other circumstances, *see, e.g., Rufus v. Seneca Mortgage Servicing*, 2017 WL 2591528, at *2 (D. Md. June 14, 2017) (*pro se* complaint ‘almost entirely incomprehensible...’), it is not a helpful label here.” *Knox v. Mayor & City Council Baltimore City*, 2017 WL 5903709, at *4 (D. Md. Nov. 30, 2017).

The Complaint satisfies FRCP 8(a)(2), which merely requires a “short and plain statement of the claim showing that the pleader is entitled to relief.” Plaintiff brings just two straightforward causes of action (failure to warn and express warranty) and supports each with specific facts against Novo Nordisk¹. *See* Complaint ¶¶ 85-140. The Complaint details how Novo Nordisk’s drug (Ozempic) affects the human body (Complaint ¶ 4), the approval process for Ozempic (Complaint ¶¶ 29-33), Novo Nordisk’s knowledge of the risk of gastroparesis (Complaint ¶¶ 56-68), how Novo Nordisk marketed Ozempic to tout safety while concealing the risk of gastroparesis (Complaint ¶¶ 34-44, 55), and how Novo Nordisk did not warn about gastroparesis in Ozempic’s label (Complaint ¶¶ 69-84).

Plaintiff has given Novo Nordisk notice of the claims against it and the factual basis for her claims. *See La. Fair Hous. Action Ctr. V. Plantation Mgmt.*, 2022 WL 204555, at *8 (E.D. La. Jan. 24, 2022) (“Plaintiff lays out its claims in a manner that introduces no ambiguity, masks no theories for recovery, and avoids lengthy and unnecessary duplication of allegations for each individual defendant accused of similar behavior.”). This Court has rejected shotgun pleading arguments where, as here, a defendant can decipher the claims against it. *Lawson*, 2017 WL

¹ Novo Nordisk appears to concede that it is proper to group the various Novo Nordisk entities together at this stage.

4365814, at *4.²

Novo Nordisk cites *Weiland v. Palm Beach Cnty. Sheriff's Off.*, 792 F.3d 1313 (11th Cir. 2015), but that case refutes its argument. The *Weiland* court held that the key issue is whether “it is *virtually impossible* to know which allegations of fact are intended to support which claim(s) for relief.” *Id.* at 1325 (emphasis by court) (citation omitted). Accordingly, the *Weiland* court rejected a similar shotgun pleading argument because, as here, the court could “understand the claims that were stated in these two counts.” *Id.* at 1324.

The Complaint appropriately incorporates all facts into each count because the basis for both counts is largely identical: namely, that Novo Nordisk knew of and concealed the risk of gastroparesis.³ See *Jones v. Herlin*, 2013 WL 823420, n.3 (W.D. La. Mar. 6, 2013) (“[M]ost, if not all of the facts are germane to each of the claims.”). Arguing otherwise, Novo Nordisk cites unhelpful cases that involved woefully deficient, bare bones, or incomprehensible complaints. See *O’Neal v. Universal Prot. Serv.*, 2022 WL 1631970, at *5–6 (M.D. La. May 23, 2022) (dismissal with leave to amend where complaint did not allege nature of disability discrimination or even nature of disability) (Complaint “contains irrelevant factual allegations and legal conclusions, states immaterial facts not obviously connected to any particular cause of action, copies wholesale

² See also *Alexander v. Dresser*, 2022 WL 509366, at *5 (W.D. La. Feb. 18, 2022) (“[B]ecause the Amended Complaint describes the facts underlying the Plaintiffs’ claims in a manner sufficient to notify Defendants of the claims against them—thereby allowing them to prepare responsive pleadings—it does not constitute an improper shotgun pleading.”); *Adams v. Walker*, 2021 WL 1894865, at *2 (E.D. La. May 11, 2021) (“Despite its length, Plaintiff’s Complaint is not a ‘shotgun pleading;’ Plaintiff very clearly brings seven distinct claims against three defendants. He supports those claims with a detailed, albeit cumbersome, recitation of facts.”).

³ Novo Nordisk argues that references to Mounjaro in the Complaint (¶¶ 46, 54) are irrelevant; however, because the risk of gastroparesis is common to the entire GLP-1RA class of drugs (including Ozempic and Mounjaro), any published literature regarding the association between gastroparesis and any GLP-1RA would have put Novo Nordisk on notice of the need to warn patients, including Plaintiff, and prescribing physicians of the risk of gastroparesis associated with these drugs. See, e.g., Complaint ¶¶ 5, 6, 46, 47–49, 55.

large swaths of statutory text without specifying which provision (if any) the Defendants are accused of violating, and indiscriminately alleges nine claims against two separate Defendants without any indication whether (or how) each Defendant is liable.”⁴

After arguing that the Complaint pleads too little about its conduct, Novo Nordisk abruptly pivots to argue that the Complaint says too much about its marketing tactics. However, it is highly relevant that Novo Nordisk promoted its product as safe while concealing the risk of a life-threatening condition, gastroparesis. In each and every communication, Novo Nordisk squandered an opportunity to inform the public and the medical community and, instead, opted for silence about gastroparesis in order to increase its market share and its bottom line.

Novo Nordisk lastly foreshadows its (erroneous) argument that Plaintiff did not fully anticipate and plead around Novo Nordisk’s learned intermediary defense, which Plaintiff fully addresses below. To the extent Novo Nordisk believes that more specificity is required, this Court has concluded that “additional information ... regarding the specific nature of Plaintiff’s claims is appropriately reserved for discovery.” *Barrett v. Dresser*, 2021 WL 53658, at *3 (W.D. La. Jan. 6, 2021).

II. Plaintiff has stated an inadequate warning claim.

For her failure-to-warn claim under the Louisiana Products Liability Act, Plaintiff must demonstrate that Ozempic “possessed a characteristic that may cause damage,” and that Novo Nordisk “failed to use reasonable care to provide an adequate warning of such characteristic and

⁴ See e.g., *Scott v. Baton Rouge*, 2023 WL 3746477, at *3-5 (M.D. La. May 31, 2023) (dismissing complaint with leave to amend) (five redundant official capacity claims against government entity, but no allegations to support a relevant *Monell* pattern or practice); *Copeland v. Axion*, 2016 WL 4250431, at *4 (S.D. Miss. Aug. 11, 2016) (dismissing complaint with leave to amend) (“...Plaintiffs name 16 separate parties, as well as John Does 1-20 and ABC Corporations 1-20,” and “Court is unable to determine which Defendants are being sued under which counts of the Complaint or what facts support Plaintiffs’ claims against each Defendant.”).

its danger to users and handlers of the product.” La. Stat. § 9:2800.57. Plaintiff also “must show that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff’s injury.” *Stahl v. Novartis*, 283 F.3d 254, 265 (5th Cir. 2002).

Here, Plaintiff has alleged that Novo Nordisk did not warn her physician of the risk that Ozempic can cause gastroparesis, Complaint ¶¶ 70, 80, 99-103; her doctor did not know of this risk, Complaint ¶¶ 105-07; and the failure to warn caused her prescriber’s decision and her resulting injury. Complaint ¶¶ 107-12, 116-18. Courts routinely find similar allegations sufficient. *See Batiste v. Stryker*, 2021 WL 1171880, at *7 (M.D. La. Mar. 26, 2021).⁵ As discussed below, Novo Nordisk’s “argument based on the ‘learned intermediary doctrine’ is premature at this stage.” *Rayford v. Karl Storz Endoscopy*, 2016 WL 4398513, at *6 (W.D. La. June 22, 2016).

A. Novo Nordisk’s learned intermediary argument is premature.

To prevail on its learned intermediary defense, Novo Nordisk must prove both that 1) the warning provides “a clear and unambiguous reference to the adverse reaction suffered by the plaintiff,” and 2) that the “prescribing physician [has] unequivocally testif[ied] that the warning was adequate to inform him or her of the risks.” *Stahl*, 283 F.3d at 267. Given the manufacturer’s evidentiary burden to show prescriber testimony, courts overwhelmingly conclude that this defense

⁵*See also e.g., Baudin v. AstraZeneca*, 413 F. Supp. 3d 498, 510 (M.D. La. 2019); *Donald v. AstraZeneca*, 2017 WL 1079186, at *3 (E.D. La. Mar. 22, 2017); *Lahaye v. AstraZeneca*, 2015 WL 1935947, at *3-5 (M.D. La. Apr. 28, 2015); *Jenkins v. Bristol-Myers*, 2015 WL 5012130, at *5 (E.D. La. Aug. 21, 2015); *Brocato v. DePuy*, 2015 WL 854150, at *6 (E.D. La. Feb. 25, 2015); *McLaughlin v. GlaxoSmithKline*, 2014 WL 669349, at *5 (W.D. La. Jan. 6, 2014) (sufficient to allege that defendant “failed to warn patients and physicians of serious problems associated with Paxil”); *Bertrand v. Eli Lilly*, 2013 WL 4093556, at *7 (W.D. La. Aug. 13, 2013); *Harris v. Merck*, 2012 WL 5384720, at *4 (W.D. La. Nov. 1, 2012); *Nelson v. Mylan*, 2010 WL 3339274, at *5 (W.D. La. Aug. 3, 2010); *R&R adopted*, 2010 WL 3363039 (Aug. 24, 2010); *Ivory v. Pfizer*, 2009 WL 3230611, at *4 (W.D. La. Sept. 30, 2009).

cannot be resolved on the pleadings. *See Brocato*, 2015 WL 854150, at *6.⁶

Additionally, “Louisiana law contains a presumption that if adequate warning is provided, that warning would have been followed, or ‘heeded.’” *In re Xarelto*, 2017 WL 1393480, at *3 (E.D. La. Apr. 17, 2017). Accordingly, there is a presumption that Plaintiff’s prescriber would have read and heeded an adequate warning. *Id.*; *see also In re Taxotere*, 2022 WL 245605, n.19 (E.D. La. Jan. 11, 2022); *Sharkey v. Sterling Drug*, 600 So. 2d 701, 711 (La. App. 1st Cir. 1992). At this stage, Novo Nordisk does not attempt to—and cannot—rebut the heeding presumption.

Plaintiff has alleged that her physician’s prescribing decision would have changed if Novo Nordisk had provided an adequate warning—even though such allegations are unnecessary. *Jenkins*, 2015 WL 5012130, at *5 (“Plaintiff is not required to detail what an adequate warning would be and how an adequate warning would have caused Plaintiff’s treating physician to act differently.”). At this stage, “Plaintiff is merely required to allege that Defendants did not adequately warn Plaintiff’s treating physician and that the inadequate warning constituted the proximate [cause] of Plaintiff’s injuries.” *Id.*; *see also Harris*, 2012 WL 5384720, at *4 (rejecting argument that plaintiff must allege what adequate warning would have stated).

Moreover, this Court must “draw all reasonable inferences in favor of the plaintiff,” *Frye*, 953 F.3d at 290-91, and the Complaint supports inferences that plaintiff’s doctor would not have prescribed Ozempic: 1) if Novo Nordisk warned that it could cause the life-threatening condition of gastroparesis, or 2) if Plaintiff objected to taking Ozempic due to the risk of gastroparesis (if

⁶ *See also Ivory*, 2009 WL 3230611, at *4 (“learned intermediary doctrine is premature”); *Rayford*, 2016 WL 4398513, at *6 (“Whether Plaintiff will ultimately be able to offer sufficient proof to support the [warning] claim is a matter the Court may more fully address within the context of a motion for summary judgment or a trial....”); *McLaughlin*, 2014 WL 669349, at *5; *Jenkins*, 2015 WL 5012130, at *5.

Novo Nordisk had warned of the risk). Complaint ¶¶ 107-12.⁷ The Complaint also supports a reasonable inference that—even if the prescriber initially prescribed Ozempic—Plaintiff’s doctor would have monitored her symptoms and gastric emptying and discontinued Ozempic before her condition became so severe that she required hospitalizations, including several emergency room visits. Complaint ¶¶ 13, 107-12. *See Mauldin v. Upjohn*, 697 F.2d 644, 647 (5th Cir. 1983) (causation is a jury question where doctor testified that warning would not have changed prescribing decision but would have led doctor to monitor patient for symptoms).

Novo Nordisk contends that Plaintiff’s “information and belief” allegations are improper as to what her prescriber would have done if presented with an adequate warning, but pleading upon information and belief is an “essential expedient when matters that are necessary to complete the statement of a claim are not within the knowledge of the plaintiff but [she] has sufficient data to justify interposing an allegation on the subject.” Wright & Miller, 5 FED. PRAC. & PROC. CIV. § 1224. Indeed, Rule 8 permits a plaintiff to plead allegations “hypothetically.” FRCP 8(d)(2)-(3). Plaintiff’s allegations are appropriate because “the allegations in the pleading raise a facially plausible claim.” *Barnett v. Patwardhan*, 2013 WL 1290201, at *2 (W.D. La. Mar. 28, 2013).

Novo Nordisk is also incorrect when it argues that Plaintiff must identify her physician by name in the complaint. *See Jenkins*, 2015 WL 5012130, at *5 (“the 12(b)(6) standard does not require Plaintiff to identify his treating physician”); *Lahaye*, 2015 WL 1935947, at *5; *Baudin*, 413 F. Supp. 3d at 510. Novo Nordisk relies upon *Kennedy v. Pfizer*, 2013 WL 4590331, at *5 (W.D. La. Aug. 28, 2013), but that case is distinguishable as there was “not even an allegation that a physician prescribed the medication.” Significantly, *Kennedy* follows the reasoning in *Harris*,

⁷In fact, it is hard to believe that Plaintiff’s doctor would have prescribed Ozempic over her objection.

which expressly rejected the argument that a plaintiff must “identify a specific prescribing physician.” 2012 WL 5384720, at *4. The difference between the two cases is that, as in this case, Harris pled causation whereas, unlike in this case, Kennedy did not.

Novo Nordisk further argues that, at this stage, this Court should reject allegations about Novo Nordisk’s inadequate testing for gastroparesis and Novo Nordisk’s failure to alert doctors to the lack of testing. Contrary to Novo Nordisk’s argument that it lacks any such duty in Louisiana, “[t]he duty to warn encompasses a duty to keep abreast of scientific knowledge and discoveries, a duty to test and inspect the product, and a duty to conduct research commensurate with the dangers of the product.” *Cole v. Ashland Chem.*, 2010 WL 5141248, at *2 (E.D. La. Dec. 10, 2010). This duty is well-established. *See Klem v. E.I. DuPont*, 19 F.3d 997, 1001 (5th Cir. 1994) (“Louisiana law requires a manufacturer not only to keep abreast of scientific developments but also to perform its own tests to determine that its products are safe.”); *Halphen v. Johns-Manville Sales*, 484 So. 2d 110, 115 (La. 1986) (“A manufacturer also has a duty to test and inspect its product, and the extent of research and experiment must be commensurate with the dangers involved.”).⁸

Arguing otherwise, Novo Nordisk relies upon two decisions: *Theriot v. Danek*, 168 F.3d 253 (5th Cir. 1999), and *Bell v. Danek*, 1999 WL 335612 (E.D. La. May 24, 1999). Both cases are distinguishable because those cases were decided at the summary judgment stage and because the doctors testified that they were fully aware of the risks at issue, rendering additional warnings unnecessary. *Theriot*, 168 F.3d at 256; *Bell*, 1999 WL 335612, at *4. Neither decision supports Novo Nordisk’s argument that, as a matter of law, it would have made no difference to Plaintiff’s doctor if Novo Nordisk had warned about its lack of testing for the risk of gastroparesis. Complaint

⁸ *See also In re FEMA Trailer Formaldehyde*, 2009 WL 2382773, at *3 (E.D. La. July 23, 2009); *Hopper v. Crown*, 646 So. 2d 933, 946 (La. App. 1st Cir. 1994) (“Crown also breached its duty to test and experiment...”); *Antley v. Yamaha*, 539 So. 2d 696, 701 (La. App. 3d 1989).

¶¶ 100, 104, 108, 110. At a minimum, Novo Nordisk’s argument is premature about the extent of its testing and the adequacy of any information provided to doctors about that testing.

B. Novo Nordisk does not satisfy either prerequisite to its learned intermediary defense.

1. Novo Nordisk does not present unequivocal prescriber testimony.

Disregarding Plaintiff’s allegation that her doctor did not know of the risk of gastroparesis (Complaint ¶ 106), Novo Nordisk erroneously takes all inferences in its own favor and assumes that it did not need to warn as every doctor on earth knew in 2022 that Ozempic can cause gastroparesis. Novo Nordisk improperly attempts to shift its burden to research the dangers of its product and to warn about those dangers. For this reason, the court rejected an identical argument in *Marks*:

OHMEDA argues that articles which appeared in trade publications were sufficient to warn the medical community. We find this is not sufficient; the duty established by La.R.S. 9:2800.57(C) is a duty placed directly upon the manufacturer. It cannot be delegated.

Marks v. OHMEDA, 871 So. 2d 1148, 1155 (La. App. 3d 2004).⁹

Moreover, Novo Nordisk does not even attempt to satisfy the “unequivocal[]” prescriber testimony element of its learned intermediary defense. *Stahl*, 283 F.3d at 267. This Court should reject Novo Nordisk’s motion because this “element is essential to the learned intermediary defense.” *Kampmann v. Mason*, 921 So. 2d 1093, 1096 (La. App. 5th 2006) (rejecting defense where manufacturer “did not present evidence from any medical professional”); *see also Timm v. Upjohn*, 624 F.2d 536, 539 & n.8 (5th Cir. 1980) (causation is a jury question where prescriber testified that he was aware of risk but also that he would not have prescribed the drug if there had

⁹ *See also id.* at 1157 (“Defendant’s ‘learned intermediary’ defense fails because OHMEDA did nothing to inform either Plaintiff’s anesthesiologist or her nurse anesthetist of the dangerous characteristic...”); *Wallace v. Upjohn*, 535 So. 2d 1110, 1116 (La. App. 1st 1988) (duty to warn where medical literature “alerted the drug companies to the *possibility*” of risk) (emphasis by court); *Miller v. Upjohn*, 465 So. 2d 42, 45 (La. App. 1st 1985) (duty to warn of risk due to adverse events and medical literature).

been a warning); *Sharkey v. Sterling Drug*, 600 So. 2d 701, 711 (La. App. 1st 1992) (same).

2. Novo Nordisk did not give any warning for gastroparesis—much less a clear and unambiguous warning.

Novo Nordisk also cannot satisfy the learned intermediary defense requirement of “a clear and unambiguous reference” to gastroparesis in the label. *Stahl*, 283 F.3d at 267. Indeed, the term “gastroparesis” never even appears in the Ozempic label.

Nevertheless, Novo Nordisk argues that it mentions *other* gastrointestinal adverse reactions like nausea and vomiting, but *listing a condition in the Adverse Reaction section is not a Warning*. It is simply a report that nausea and vomiting have occurred and there is “some basis to believe” that it is caused by the drug. 21 C.F.R. § 201.57(c)(7). The Adverse Reaction section thus unquestionably is not a discharge of a duty to warn. *See Merck v. Albrecht*, 139 S. Ct. 1668, 1673 (2019) (explaining that “Adverse Reactions” section on label identifies less serious risks than “Warnings and Precautions” section); *see also Mattos v. Eli Lilly*, 2012 WL 1893551, at *5 (D. Kan. May 23, 2012) (rejecting argument that mention of condition in Adverse Reactions section is adequate warning as a matter of law). As the Fifth Circuit has held, “a mere reference to an adverse effect is not necessarily an adequate warning” because “[t]he warning must contain language that is adequate to reasonably inform the recipient (i.e., the doctor in a learned intermediary case) about the nature of the danger involved.” *Stahl*, 283 F.3d at 267. *See also Thom v. Bristol-Myers Squibb*, 353 F.3d 848, 853 (10th Cir. 2003) (“The mere mention of a possible injury, however, is not necessarily adequate.”). In any event, mention of vomiting and nausea—which can be associated with a large variety of underlying causes—does not warn doctors that gastroparesis, a paralysis of the stomach and thus a paralysis of digestion, is one of the possible underlying causes.

Novo Nordisk further argues that the label indicates that Ozempic “delays gastric emptying.” However, the label does not mention delayed gastric emptying in the Warnings section,

indicating that Novo Nordisk was merely describing the drug's mechanism and not warning that Ozempic can cause gastroparesis. *See* 21 C.F.R. §§ 201.57(b)(a)(10) and 201.57(c)(6) (requirements for "Warnings and Precautions"). Moreover, the mention of "delayed gastric emptying" is not an "a clear and unambiguous reference" to gastroparesis, which is a highly dangerous condition. *Stahl*, 283 F.3d at 267.

Novo Nordisk cites just a single case granting dismissal based upon the learned intermediary defense.¹⁰ *See Thomas v. Bracco Diagnostics*, 2020 WL 1016273 (W.D. La. Feb. 27, 2020), *report & recommendation adopted without objection*, 2020 WL 1243389 (W.D. La. Mar. 13, 2020). However, Thomas alleged that "the radiology community" was on "high alert," *and* that the label "warn[ed] of the exact issue which [wa]s the subject of [his] failure to warn claim." *Id.* Here, Novo Nordisk does not warn that Ozempic can cause gastroparesis, and Plaintiff does not allege that the medical community was on "high alert" of the risk. Just the opposite.¹¹ Thus, *Thomas* is distinguishable. *See Holbrook v. Boston Sci.*, 487 F. Supp. 3d 100, 110 (D. Mass. 2020) ("Unlike *Thomas*, the Holbrooks' physician was not already on high alert...").

At this stage, this Court should reject Novo Nordisk's argument that its label is adequate as a matter of law. *See Guidry v. Janssen*, 206 F. Supp. 3d 1187, 1199 (E.D. La. 2016) ("Whether the defendants' warnings were adequate... goes beyond the scope of a motion to dismiss..."); *Baudin*, 413 F. Supp. 3d at 510 ("[T]he sufficiency of the warning is not before the Court at this motion to dismiss stage..."). Novo Nordisk's learned intermediary defense is premature as it cannot show an unambiguous gastroparesis warning or unequivocal prescriber testimony.

¹⁰ Novo Nordisk primarily relies on distinguishable *summary judgment* decisions. *Stahl*, 283 F.3d at 266, 268 (doctor testified that warning was adequate); *In re Taxotere (Phillips)*, 994 F.3d 704, 709 (5th Cir. 2021) (doctor testified that stronger warning would not have made a difference); *In re Taxotere (Gahan)*, 859 F. App'x 692, 694 (5th Cir. 2021) (doctor testified that she knew of risk).

¹¹ Complaint ¶¶ 106-07 ("Plaintiff's prescribing physician(s) had no way to determine the truth.").

III. Plaintiff has stated an express warranty claim.

This Court has found express warranty allegations sufficient where, as here, a drug manufacturer warrants the safety of its product in marketing materials or otherwise, and its statements are contrary to its knowledge. *Kaylor v. Eisai*, 2022 WL 983657, at *5 (W.D. La. Mar. 20, 2022); *see also Guidry*, 206 F. Supp. 3d at 1199 (“[M]arketing materials may rise to the level of an express warranty if they make claims as to the product’s safety.”). In *Kaylor*, this Court permitted a claim based upon allegations that 1) defendants stated that their drug was “safe”, 2) the drug can cause cancer, and 3) defendants knew of the risk. 2022 WL 983657, at *5. The Court concluded that medical literature showing the cancer risk supported an inference that defendants suppressed information and induced patients to “use the drug under the ruse of safety.” *Id.*

As in *Kaylor*, Plaintiff relies on the express warranties Novo Nordisk made to Plaintiff and her physician about Ozempic by way of “websites, in press releases, through in-person presentations, through the drug’s label, in print materials, on social media, and through other public outlets.” Complaint ¶¶ 29-33, 36-44, 121-122. Novo Nordisk marketed Ozempic through various mediums and warranted that Ozempic was safe to improve glycemic control. *See, e.g.*, Complaint ¶¶ 29-33, 36-44, 121-122. As in the cases cited above, Plaintiff has alleged that Novo Nordisk knew of studies that GLP-1RAs (like Ozempic) can cause gastroparesis, that Novo Nordisk’s statements about safety downplayed and concealed that risk, and that these misrepresentations induced Plaintiff and her physician to use and prescribe Ozempic under the ruse of safety. Complaint ¶¶ 48-68, 122-125, 131-133. Courts have found similar allegations sufficient. *See Boutte v. Stryker*, 67 F. Supp. 3d 732, 738-39 (M.D. La. 2014) (defendant represented that product was “‘safe and effective’ while knowing that the combined use of its products remained untested, ineffective, and unsafe”); *Baudin*, 413 F. Supp. 3d at 512 (defendant represented that drug was tested, safe, and effective despite knowledge to contrary).

Courts have also permitted claims when a plaintiff alleges that “a manufacturer suppressed information, gained a significant market share with false representations, or induced persons to use [a] drug under the ruse of safety, with knowledge that the drug is dangerous.” *Kaylor*, 2022 WL 983657, at *5; *see also Huffman v. Squibb*, 2016 WL 6024532, *3 (E.D. La. Oct. 14, 2016) (rejecting argument “that advertisements can never contain an express warranty”) (defendants stated drug was superior to others, but was more dangerous); *Harris*, 2012 WL 5384720, at *5 (false marketing statements grew market share); *Baudin*, 413 F. Supp. 3d at 512; *Boutte*, 67 F. Supp. 3d at 738-39; *Guidry*, 206 F. Supp. 3d at 1199-1200. As in these cases, this Court should deny Novo Nordisk’s motion because Plaintiff alleges that Novo Nordisk gained a significant market share due to its false representations about Ozempic’s safety. Complaint ¶¶ 34-44, 55.¹²

Novo Nordisk cites *Robertson v. AstraZeneca*, 2015 WL 5823326, at *5 (E.D. La. Oct. 6, 2015), to argue that marketing materials are irrelevant. For this proposition, *Robertson* relied upon *Becnel v. Mercedes-Benz*, 2014 WL 4450431, at *5 (E.D. La. Sept. 10, 2014). *Becnel*, in turn, cited *Scott v. Am. Olean Tile*, 706 So. 2d 1091 (La. App. 3d 1998). However, *Scott* does not stand for this proposition, and instead held that there was no evidence to contradict the defendant’s statement that its mats are slip resistant. *Id.* at 1095. Accordingly, and especially at this early stage, *Boutte*, *Baudin*, *Guidry*, *Huffman*, *Harris*, and *Kaylor* are more persuasive than *Robertson* and *Becnel*.

¹² Novo Nordisk relies on distinguishable cases where the plaintiff alleged that the defendant made statements that its product was safe, but the plaintiff did not allege how the product was unsafe (i.e., that defendant’s statements were false) or allege that the false statements led to plaintiff’s use of the product (i.e., causation). *See Corley v. Stryker*, 2014 WL 3375596, *5-6 (W.D. La. May 27, 2014), *report and recommendation adopted without objection from plaintiff*, 2014 WL 3125990 (July 3, 2014) (alleged statement that product was safe, but did not allege how statement was false or that the statement led to plaintiff’s use of product); *Fuller v. Eisai*, 513 F. Supp. 3d 710, 723 (E.D. La. 2021) (alleged that “Belviq was approved by the FDA” and did not allege that statement reached plaintiff or prescriber); *Doe v. AstraZeneca*, 2015 WL 4661814, at *4 (E.D. La. Aug. 5, 2015) (alleged statements that product was safe but did not allege how statement was false).

Finally, contrary to Novo Nordisk's argument, Plaintiff has specifically alleged that Novo Nordisk induced her and her physician through its label and marketing to use and prescribe Ozempic, and that but for these express warranties, she would not have used Ozempic and her physician would not have prescribed it. Complaint ¶¶ 34-44, 121-123, 134. This case is nothing like *Thomas*, on which Novo Nordisk relies, as the label in that case contradicted the plaintiff's allegations about the warnings within the label. 2020 WL 1016273, at *6-7, *report & recommendation adopted without objection*, 2020 WL 1243389. This Court should instead follow the numerous cases that have found similar causation allegations sufficient. *See Guidry*, 206 F. Supp. 3d at 1199-1200; *Kaylor*, 2022 WL 983657, at *5; *Harris*, 2012 WL 5384720, at *5; *Boutte*, 67 F. Supp. 3d at 738-39; *Baudin*, 413 F. Supp. 3d at 512.

IV. This Court should reserve judgment on punitive damages.

Louisiana choice-of-law statutes permit application of state law on an issue-by-issue basis, *Energy Coal v. CITGO*, 836 F.3d 457, 459 (5th Cir. 2016), and thus another state's laws may govern punitive damages. The states in which the Novo Nordisk entities are incorporated or where its misconduct occurred have an interest in punishing any reprehensible conduct within their borders. However, Novo Nordisk's motion to dismiss punitive damages is premature, and the record should be developed to know the nature, extent, and location of any conduct warranting punishment.

The choice-of-law inquiry is fact specific. *In re Phenylpropanolamine (PPA)*, 2004 WL 7332793, at *3 (W.D. Wash. June 10, 2004) (denying motion to dismiss "as to those plaintiffs who have asserted a claim for punitive damages purporting to rely on Louisiana's choice-of-law statute and the punitive damages laws of other states"); *New Orleans Assets v. Carl E. Woodward*, 278 F. Supp. 2d 776, 780-81 (E.D. La. 2003) (denying motion for partial summary as to punitive damages

due to factual questions).¹³ Under La. Civ. Code art. 3545, Louisiana law generally governs punitive damages for injuries in this state, but La. Civ. Code art. 3547 creates an exception where,

from the totality of the circumstances of an exceptional case, it is clearly evident under the principles of Article 3542, that the policies of another state would be more seriously impaired if its law were not applied to the particular issue.

The principles set forth in Article 3542 include:

(1) the pertinent contacts of each state to the parties and the events giving rise to the dispute, including the place of conduct and injury, the domicile, habitual residence, or place of business of the parties, and the state in which the relationship, if any, between the parties was centered; and (2) the policies referred to in Article 3515, as well as the policies of deterring wrongful conduct and of repairing the consequences of injurious acts.

The policies in Article 3515, in turn, include:

(1) the relationship of each state to the parties and the dispute; and (2) the policies and needs of the interstate and international systems, including the policies of upholding the justified expectations of parties and of minimizing the adverse consequences that might follow from subjecting a party to the law of more than one state.

A decision requires the Court to review “the totality of the circumstances,” *Duhon v. Union Pac.*, 43 F.3d 1011, 1018 (5th Cir. 1995), and “compar[e] the policies and interests” of multiple states. *Cain v. Altec*, 236 F. App’x 965, 969-70 (5th Cir. 2007). The laws of a state other than Louisiana may apply because “punitive damages has more to do with the tortfeasor than with the victim,” *Racko Prop. v. Alaba. Great S.*, 2008 WL 754684, at *4 (E.D. La. Mar. 19, 2008), but the choice-of-law analysis requires a developed record to weigh several factors about the nature, extent, and location of Novo Nordisk’s conduct warranting punitive damages.¹⁴ Accordingly, this Court should deny Novo Nordisk’s motion to dismiss the punitive damages claim as premature.

CONCLUSION

For these reasons, this Court should deny Novo Nordisk’s motion to dismiss.

¹³ Plaintiff agrees with Novo Nordisk that Louisiana law governs liability issues.

¹⁴ Plaintiff concedes that attorney fees are unavailable.

Dated: December 4, 2023

Respectfully Submitted,

**COX, COX, FILO CAMEL, WILSON
& BROWN, LLC**

s/ Somer G. Brown

MICHAEL K. COX (22026)

SOMER G. BROWN (31462)

723 Broad Street

Lake Charles, LA 70601

(337) 436-6611 phone

(337) 436-9541 fax

CERTIFICATE OF SERVICE

I hereby certify that on the date set forth above the foregoing was filed via the Court's ECF/CM filing system which electronically served all counsel of record.

s/ Somer G. Brown

SOMER G. BROWN